NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 12 June 2018 (#18)

[Click on blue hyperlink for further information]

*The NIH funding opportunities listed below are only a **selection** of pre-screened, currently open health funding opportunities for which **South African institutions are eligible to apply**. For a comprehensive selection of NIH funding opportunities, please visit www.grants.nih.gov.*

Confirm your intent to apply ASAP, but not later than 30 days before the submission date.

Contact: RGMO Pre-Awards cdevries@sun.ac.za

Important Notices:

- **Request for Information on the Development of the FY 2021-2023 Trans-NIH Plan for HIV-Related Research (NOT-OD-18-185)**
- **Findings of Research Misconduct (NOT-OD-18-189)**

1. Approaches for Understanding Disease Mechanisms and Improving Outcomes in TB Meningitis (TBM) (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-822) **Type:** ***R01***
Application Due Date: September 4, 2018, September 4, 2019, September 4, 2020 for all types of non-AIDS and AIDS and AIDS-related applications. Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to invite applications for support of innovative clinical and preclinical/non-clinical research to improve our understanding of disease mechanisms in tuberculosis meningitis (TBM) and to improve therapy in the presence or absence of human immunodeficiency virus (HIV) co-infection.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

2. Strengthening Global Competency and Capacity in Inspectional Approaches and Good Manufacturing Practices (GMP)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-FD-18-024) **Type:** ***U01***
Application Due Date: August 13, 2018, by 11:59 PM ***Eastern Time.***
Funding Opportunity Announcement: The Cooperative Agreement will build upon the extensive experience of an institution with well-established and globally recognized collaboration with inspectorates of National Regulatory Authorities (NRAs) around the globe in support of data-driven and science-based regulatory and public health strategies and approaches that align with FDA domestic and global priorities to assure a pharmaceutical quality integration of assessment, inspection, policy, and research activities within a pharmaceutical context, including Good Manufacturing Practices (GMP). The funding will catalyze and support the institution's activities that are focused on consensus around what optimal good manufacturing practices are and the competencies for Inspectors within the context of emerging and increasingly complex science, research and innovation in manufacturing of pharmaceutical products. Based on such consensus, the institution and its network of NRA Inspectorates will work toward a systems-approach and sustainable alignment across and among NRA Inspectorates in GMP quality manufacturing.
Budget: Application budgets need to reflect the actual needs of the proposed project and should not exceed $300 000 in total costs (direct and indirect) per annum. The scope of the proposed project should determine the project period. The maximum project period is five (5) years.

3. Rare Genetic Syndromes as a Window into the Genetic Architecture of Mental Disorders (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-19-200) **Type:** ***U01***
Application Due Date: August 9, 2018, by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: This initiative will foster collaborative and coordinated efforts to characterize the underlying genetic architecture of diverse neuropsychiatric phenotypes within and across rare genetic disorders and identify the shared genetic risk across rare and idiopathic neuropsychiatric disorders. Projects from multi-disciplinary teams will utilize genome-wide data to comprehensively assess the contribution of genetic variation to the variable expressivity and incomplete penetrance of neuropsychiatric phenotypes across rare genetic disorders. Projects are encouraged to leverage existing resources, cohorts, and collaborative networks with established infrastructure for consistent and high-quality phenotypic data collection and genomic data generation. Projects should seek to enhance the quality of the phenotypic data available for rare genetic disorders by developing or applying phenotyping methodologies that create a pipeline for standardizing assessments and that cut across rare genetic disorders and across developmental time points. Under this initiative, investigators will form a network to facilitate data sharing and harmonization of clinical and genetic

data across different studies within the network, as well as accelerate characterization of genotype to phenotype relationships across rare genetic disorders. This network will also generate a resource of bio-samples, as well as phenotypic and genetic data for broader dissemination to the scientific community. This FOA should be used for applications that are not collaborative between sites. Applications requiring two or more collaborating sites to complete the proposed research should apply as a linked set of collaborative U01 applications to the companion collaborative U01 FOA (RFA-MH-19-201). All awards supported under this FOA and the companion collaborative U01 FOA (RFA -MH-19-201) will be governed by the Mental Health Rare Genetic Disease Network (MHRGDN).
Budget: NIMH and NICHD intend to commit a total of at least $4,500,000 in FY 2019 to fund a total of 3-5 applications under this FOA and the companion FOA (RFA-MH-19-201). The total amount awarded and the number of awards will depend upon the quality, duration, costs and the receipt of a sufficient number of meritorious applications. Application budgets are not limited but need to reflect the actual needs of the proposed project. The project period is limited to 5 years.

4. Rare Genetic Syndromes as a Window into the Genetic Architecture of Mental Disorders (*Collaborative* - Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-19-201) **Type: *U01***
Application Due Date: August 9, 2018, by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: This initiative will foster collaborative and coordinated efforts to characterize the underlying genetic architecture of diverse neuropsychiatric phenotypes within and across rare genetic disorders and identify the shared genetic risk across rare and idiopathic neuropsychiatric disorders. Projects from multi-disciplinary teams will utilize genome-wide data to comprehensively assess the contribution of genetic variation to the variable expressivity and incomplete penetrance of neuropsychiatric phenotypes across rare genetic disorders. Projects are encouraged to leverage existing resources, cohorts, and collaborative networks with established infrastructure for consistent and high-quality phenotypic data collection and genomic data generation. Projects should seek to enhance the quality of the phenotypic data available for rare genetic disorders by developing or applying phenotyping methodologies that create a pipeline for standardizing assessments and that cut across rare genetic disorders and across developmental time points. Under this initiative, investigators will form a network to facilitate data sharing and harmonization of clinical and genetic data across different studies within the network, as well as accelerate characterization of genotype to phenotype relationships across rare genetic disorders. This network will also generate a resource of bio-samples, as well as phenotypic and genetic data for broader dissemination to the scientific community. This FOA should be used when two or more collaborating sites are essential to conduct the proposed research. It is required that the Research Strategy be identical across linked collaborative U01 applications, with the exception of a short section describing the specific function of each application under "elements unique to this site." The Human Subjects section for each application should be specific to the research conducted at that site. For a linked set of collaborative U01 applications, each application must have its own Program Director/Principal Investigator (PD/PI) and the program must provide a mechanism for cross-site coordination. Applications from a single-site should be submitted under the companion FOA (RFA-MH-18-200). All awards supported under this FOA and the companion collaborative U01 FOA (RFA-MH-19-200) will be governed by the Mental Health Rare Genetic Disease Network (MHRGDN).
Budget: NIMH and NICHD intend to commit a total of at least $4,500,000 in FY 2019 to fund a total of 3-5 applications under this FOA and the companion FOA (RFA-MH-19-200). The total amount awarded and the number of awards will depend upon the quality, duration, costs and the receipt of a sufficient number of meritorious applications. Application budgets are not limited but need to reflect the actual needs of the proposed project. The project period is limited to 5 years.

5. Analyses of CALERIE Data and Biospecimens to Elucidate Mechanisms of Caloric Restriction (CR)-Induced Effects in Humans (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-823) **Type: *R01***
Application Due Date: Standard dates apply, by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The National Institute on Aging (NIA) invites applications for research projects (R01) involving secondary analyses of data and/or stored biospecimens from the CALERIE (Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy) trial. The goal of this funding opportunity announcement (FOA) is to encourage analyses that will lead to a more detailed understanding of the effects of caloric restriction (CR) on risk factors for chronic diseases, as well as, the cellular/molecular mechanisms mediating the effects of sustained CR in humans.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. A project period of up to 5 years may be requested.

6. Exploratory Analyses of CALERIE Data and Biospecimens to Elucidate Mechanisms of Caloric Restriction (CR)-Induced Effects in Humans (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-824) **Type: *R21***
Application Due Date: Standard dates apply, by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The National Institute on Aging (NIA) invites applications for new exploratory research projects (R21) involving secondary analyses of data and/or stored biospecimens from the CALERIE (Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy) trial. The goal of this funding opportunity announcement (FOA) is to encourage analyses that will lead to a more detailed understanding of the effects of caloric restriction (CR) on risk factors for chronic diseases, as well as, the cellular/molecular mechanisms mediating the effects of sustained CR in humans.
Budget: The combined budget for direct costs for the two-year project period may not exceed $275,000. No more than $200,000 may be requested in any single year. A project period of up to 2 years may be requested.

7. Analyses of Adherence Strategies and Data Sets from CALERIE to Explore Behavioral and Psychosocial Aspects of Sustained Caloric Restriction in Humans (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-825) **Type:** ***R01***

Application Due Date: Standard dates apply, by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The National Institute on Aging (NIA) invites applications for research projects (R01) involving secondary analyses of data in the Computerized Tracking System (CTS) database from the CALERIE (Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy) trial to explore behavioral and psychosocial aspects of sustained caloric restriction (CR) in humans, including the translation of the CR adherence strategies used in the trial to promote healthy behaviors, especially for the prevention of weight gain with age. CALERIE was the first trial in humans to specifically focus on the effects of sustained CR. It demonstrated feasibility of sustained human CR (for at least two years) and favorable effects on predictors of longevity, as well as on cardiometabolic risk factors. The sustained weight loss in CALERIE has not been previously attained in any clinical study in non-obese individuals.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. A project period of up to 5 years may be requested.

8. Exploratory Analyses of Adherence Strategies and Data Sets from CALERIE to Investigate Behavioral and Psychosocial Aspects of Sustained Caloric Restriction in Humans (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-826) **Type:** ***R21***

Application Due Date: Standard dates apply, by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The National Institute on Aging (NIA) invites applications for new exploratory research projects (R21) involving secondary analyses of data in the Computerized Tracking System (CTS) database from the CALERIE (Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy) trial to explore behavioral and psychosocial aspects of sustained caloric restriction (CR) in humans, including the translation of the CR adherence strategies used in the trial to promote healthy behaviors, especially for the prevention of weight gain with age. CALERIE was the first trial in humans to specifically focus on the effects of sustained CR. It demonstrated feasibility of sustained human CR (for at least two years) and favorable effects on predictors of longevity, as well as on cardiometabolic risk factors. The sustained weight loss in CALERIE has not been previously attained in any clinical study in non-obese individuals.

Budget: The combined budget for direct costs for the two-year project period may not exceed $275,000. No more than $200,000 may be requested in any single year. A project period of up to 2 years may be requested.

9. Alzheimer's Drug-Development Program (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-820) **Type:** ***U01***

Application Due Date: Standard dates and Standard AIDS dates apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The goal of this Funding Opportunity Announcement (FOA) is to provide funding support for the pre-clinical and early stage clinical (Phase I) development of novel small-molecule and biologic therapeutic agents that prevent Alzheimer's disease (AD), slow its progression or treat its cognitive and behavioral symptoms. Participants in this program will receive funding for therapy development activities such as medicinal chemistry, pharmacokinetics (PK), Absorption, Distribution, Metabolism, Excretion, Toxicology (ADMET), efficacy in animal models, formulation development, chemical synthesis under Good Manufacturing Practices (GMP), Investigational New Drug (IND) enabling studies and initial Phase I clinical testing. This program does not support research on basic mechanisms of disease, mechanisms of drug action, development of biomarkers, devices, non-pharmacological interventions (e.g., exercise, diet, cognitive training), repurposed drugs and combinations therapies, or discovery activities such as high throughput screening and hit optimization.

Budget: Application budgets are limited to $1,000,000 in direct costs per year and need to reflect the actual needs of the proposed project. For Early Stage projects, the project period is limited to five years. For Late Stage projects, the project period is limited to three years.

Brief definitions of some NIH grant mechanisms: ***comprehensive list of extramural grant and cooperative agreement activity codes***